

**What is claimed is:**

1. A device for delivering fluid to a patient, comprising:
  - A) an exit port assembly adapted to connect to a transcutaneous patient access tool; and
  - B) a dispenser including at least two laminated layers of material defining a passageway connected to the exit port assembly, and an expandable accumulator in fluid communication with the passageway.
2. A device according to Claim 1, wherein at least one layer of the dispenser comprises a resilient diaphragm.
3. A device according to Claim 2, wherein the at least two laminated layers of the dispenser further comprise:
  - a first layer;
  - a second layer received against the first layer, the second and the first layers including at least one groove defining the passageway connected to the exit port assembly, the second layer including an opening in fluid communication with the passageway, and wherein the resilient diaphragm is received on the second layer covering the opening; and
  - a third layer received over the diaphragm on the second layer, the third layer having a pulse chamber over the diaphragm and in alignment with the opening of the second layer, and a port in fluid communication with the pulse chamber.
4. A device according to Claim 3, wherein the pulse chamber has a predetermined volume.

5. A device according to Claim 3, wherein one of the second and the third layers defines a recess receiving the diaphragm, and wherein the recess has a depth about equal to a thickness of the diaphragm such that the diaphragm is secured in a substantially fluid-tight manner between the second and the third layers.

6. A device according to Claim 5, wherein a length and a width of the recess are greater than a length and a width of the diaphragm.

7. A device according to Claim 2, wherein the at least two laminated layers of the dispenser further comprise:

a first layer defining the passageway connected to the exit port assembly and an opening in fluid communication with the passageway, and wherein the resilient diaphragm is received on the first layer covering the opening;

a second layer received over the diaphragm on the first layer, the second layer having a pulse chamber over the diaphragm and in alignment with the opening of the first layer, and a port in fluid communication with the pulse chamber; and

a third layer received on the second layer and defining a secondary chamber in fluid communication with the port of the second layer.

8. A device according to Claim 3, further comprising a spring biasing the diaphragm away from the pulse chamber.

9. A device according to Claim 2, wherein the at least two laminated layers of the dispenser further comprise:

a first layer having a surface defining a recess and a groove extending from the recess;

wherein the resilient diaphragm is received on the surface of the first layer such that the recess and the diaphragm define the expandable accumulator and the groove and the diaphragm define the passageway connected to the exit port assembly.

10. A device according to Claim 7, wherein the surface of the first layer further defines a valve seat in the groove.

11. A device according to Claim 7, wherein the surface of the first layer further defines an occlusion sensor recess in the groove.

12. A device according to Claim 7, wherein the surface of the first layer further defines a reservoir and a second groove extending between the reservoir and the accumulator.

13. A device according to Claim 12, wherein the surface of the first layer further defines a bubble removal bay and a third groove extending between the bubble removal bay and the reservoir.

14. A device according to Claim 2, wherein the at least two laminated layers of the dispenser further comprise:

a first layer; and

a second layer received against the first layer, at least one the second and the first layers having a groove defining the passageway connected to the exit port assembly, the second layer including a surface facing away from the first layer and having a recess, and an opening providing fluid communication between the recess and the passageway;

wherein the resilient diaphragm is received on the second layer covering the recess to form the expandable accumulator.

15. A device according to Claim 14, further comprising an actuator for pushing the diaphragm into the recess to reduce the volume of the accumulator.
16. A device according to Claim 15, wherein the actuator comprises a rotatable cam.
17. A device according to Claim 14, further comprising:
  - a third layer received against the diaphragm and on the second layer and having a bore aligned with the recess of the second layer; and
  - wherein the actuator comprises a piston slidably received in the bore.
18. A device according to Claim 17, further comprising a magnetic coil received in the third layer coaxial with the piston for biasing the piston against the diaphragm upon being energized.
19. A device according to Claim 17, further comprising:
  - a fourth layer received against the third layer and having a bore aligned with the bore of the third layer; and
  - wherein the dispenser includes a gas generator received in the bore of the fourth layer for pressurizing the bore and biasing the piston against the diaphragm upon being actuated.
20. A device according to Claim 17, comprising multiple accumulators arranged sequentially with respect to the passageway.
21. A device according to Claim 2, wherein the at least two laminated layers of the dispenser further comprise:

first and second layers wherein the diaphragm is positioned between the layers, and one of the layers has a groove defining the passageway connected to the exit port assembly, and the other of the layers has a recess separated from the passageway by the diaphragm; and

the dispenser further includes an actuator received in the recess for pushing the diaphragm into the passageway upon being actuated.

22. A device according to Claim 21, wherein the actuator comprises a piece of piezoelectric material arranged to push the diaphragm upon the piezoelectric material assuming one of a deformed state and an undeformed state.

23. A device according to Claim 22, comprising multiple pieces of piezoelectric material arranged sequentially with respect to the passageway.

24. A device according to Claim 1, wherein the at least two laminated layers of the dispenser comprise:

a first layer;

a second layer received against the first layer, the second and the first layers defining the passageway connected to the exit port assembly, and one of the layers including a bore communicating with the passageway; and

the dispenser further includes a piston slidably received in the bore.

25. A device according to Claim 24, wherein the dispenser further comprises a spring biasing the piston towards the passageway.

26. A device according to Claim 24, wherein the dispenser further comprises a magnetic coil received in one of the layers coaxial with the piston for biasing the piston one of towards and away from the passageway upon being energized.

27. A device according to Claim 1, further comprising an inlet valve controlling flow from a reservoir into the accumulator, and an outlet valve controlling flow between the accumulator and the exit port assembly.

28. A device according to Claim 27, wherein the passageway includes openings for the valves and the valves each include a layer of resilient fluid-tight material covering the opening and a layer of piezoelectric material covering the layer of resilient fluid-tight material and arranged such that upon the piezoelectric material assuming one of a deformed state and an undeformed state, the layer of piezoelectric material forces the layer of resilient fluid-tight material into the opening of the passageway and substantially closes the passageway.

29. A device according to Claim 27, wherein the dispenser further includes a bar extending parallel with the passageway and pivotally mounted about a pivot point, and wherein the valves comprise gates extending from the bar into the passageway on opposite sides of the pivot point.

30. A device according to Claim 27, wherein the valves comprise one-way valves.

31. A device according to Claim 30, wherein the valves comprise duck bill valves.

32. A device according to Claim 1, wherein the laminated layers further define a bore bisecting the passageway and the dispenser further comprises a valve assembly including:

a valve member movably received in the bore and including an opening;

a spring biasing the valve member such that the opening of the valve member is normally offset from the passageway and the passageway is blocked by the valve member; and

an actuator for moving the valve member upon being actuated such that the opening of the valve member aligns with the passageway.

33. A device according to Claim 32, wherein the actuator comprises a gas generator for pressurizing the bore upon being actuated.

34. A device according to Claim 1, further comprising a reservoir, and the dispenser controls fluid flow from the reservoir to the exit port assembly.

35. A device according to Claim 34, wherein the reservoir contains a therapeutic fluid.

36. A device according to Claim 34, further comprising a fill port connected to the reservoir.

37. A device according to Claim 34, wherein the reservoir is pressurized.

38. A device according to Claim 1, further comprising a transcutaneous patient access tool connected to the exit port assembly.

39. A device according to Claim 1, further comprising:

a local processor connected to the dispenser and programmed to cause the dispenser to allow fluid flow from a reservoir to the exit port assembly based on flow instructions;

a wireless receiver connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor; and

a housing containing the exit port assembly, the dispenser, the local processor, and the wireless receiver, wherein the housing is free of user input components for providing flow instructions to the local processor.

40. A system including a fluid delivery device according to Claim 39, and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user interface components connected to the remote processor for allowing a user to provide flow instructions to the remote processor; and

a transmitter connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device.

41. A device according to Claim 1, further comprising:

a local processor connected to the dispenser and programmed to cause the dispenser to allow fluid flow from a reservoir to the exit port assembly based on flow instructions, and further programmed to provide flow information;

a wireless transmitter connected to the local processor for transmitting the flow information from the local processor to a separate, remote control device; and

a housing containing the exit port assembly, the dispenser, the local processor, and the wireless transmitter, wherein the housing is free of user output components for providing the flow information from the local processor to a user.

42. A system including a fluid delivery device according to Claim 41 and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user output components connected to the remote processor for allowing a user to receive flow information; and

a receiver connected to the remote processor for receiving the flow information from the transmitter of the fluid delivery device.

43. A device according to Claim 1, further comprising:

an inlet valve connected to an inlet of the accumulator;

a outlet valve connecting an outlet of the accumulator to the exit port assembly; and

a priming mechanism for maintaining the inlet valve and the outlet valve simultaneously open.

44. A device according to Claim 43, wherein the priming mechanism comprises:

a pivotally movable first link operatively connected to the inlet valve such that the inlet valve is opened upon pivoting movement of the first link;

a pivotally movable second link operatively connected to the outlet valve such that the outlet valve is opened upon pivoting movement of the second link; and

a movable priming rod operatively connected to the first and the second links for pivoting the links upon movement of the rod.

45. A device according to Claim 44, wherein:

the inlet and the outlet valves each include a valve member movable between open and closed positions;

the first link extends between the valve member of the inlet valve and the priming rod and is pivotally movable about a pivot point of the first link located between the valve member of the inlet valve and the priming rod;

the second link extends between the valve member of the outlet valve and the priming rod and is pivotally movable about a pivot point of the second link located between the valve member of the outlet valve and the priming rod; and

the priming rod is linearly movable.

46. A device according to Claim 44, further comprising:

a fill port adapted to receive a needle; and

a collar connected to the priming rod and received in the fill port, the collar adapted to receive a needle inserted into the fill port so that the inserted needle causes movement of the collar and the priming rod and pivoting movement of the links.

47. A device according to Claim 1, wherein the exit port assembly comprises a transcutaneous access tool having a known internal fluid volume.

48. A device according to claim 47, further comprising a processor controlling the dispenser, and wherein the processor is programmed to cause the dispenser to deliver a volume of fluid equal to the known internal fluid volume of the access tool upon receiving a command.

49. A device according to claim 47, further comprising a flow detector positioned between the dispenser and the access tool.

50. A device according to claim 49, further comprising a processor controlling the dispenser and receiving signals from the flow detector, and wherein the processor is programmed to cause the dispenser to deliver a predetermined flow of fluid for a predetermined period upon receiving a command and upon receiving a signal from the flow detector indicative of an initial flow of fluid to the access tool, the predetermined flow of fluid for the predetermined period producing a volume of fluid substantially equal to the known internal fluid volume of the access tool.

51. A device according to claim 47, further comprising a fluid detector positioned between the dispenser and the access tool.

52. A device according to claim 51, further comprising a processor controlling the dispenser and receiving signals from the fluid detector, and wherein the processor is programmed to cause the dispenser to deliver a predetermined volume of fluid upon receiving a command and upon receiving a signal from the fluid detector indicative of fluid initially entering the fluid detector, the predetermined volume of fluid substantially equal to the known internal fluid volume of the access tool.

53. A device according to claim 47, wherein the access tool comprises a needle.

54. A device according to Claim 1, further comprising a gas removal filter connected to the dispenser for removing gas bubbles from fluid entering the dispenser.

55. A device according to Claim 1, further comprising:

a reservoir, and the dispenser controls fluid flow from the reservoir to the exit port assembly;

a fill port; and

a gas removal filter connecting the fill port to the reservoir.

56. A device according to Claim 1, further comprising a gas permeable reservoir for containing fluid, and the dispenser controls fluid flow from the reservoir to the exit port assembly.

57. A device according to Claim 1, further comprising:

a reservoir, and the dispenser controls fluid flow from the reservoir to the exit port assembly; and

a fill port including,

    a passageway in fluid communication with the reservoir,

    a valve positioned within the passageway and allowing one-way flow into the reservoir, and

    a removable septum sealing the passageway.

58. A device according to Claim 57, wherein the fill port further comprises a funnel having a small open end removably received in the passageway and a large open end receiving the septum.

59. A device according to Claim 58, wherein the fill port further comprises a first wall having an opening removably receiving the large open end of the funnel when the small open end of the funnel is removably received in the passageway.

60. A device according to Claim 59, wherein the fill port further comprises a second wall spaced from the first wall more than a thickness of the septum and having an opening allowing passage of a needle and preventing passage of the septum.

61. A device according to Claim 57, wherein the fill port further comprises a first wall having an opening preventing passage of the septum, and a second wall spaced from the first wall at least about a thickness of the septum and having an opening allowing passage of a needle, and wherein the second wall and the opening of the second wall are adapted to allow passage of the septum upon at least a predetermined force applied to the septum.

62. A device according to Claim 61, wherein the predetermined force is less than a force required to pull a needle out of the septum.

63. A device according to Claim 1, wherein the exit port assembly comprises a plurality of exit port assemblies and each assembly comprises an independently deployable transcutaneous access tool adapted to provide fluid communication with the dispenser upon deployment.

64. A device according to claim 63, wherein each access tool comprises a needle.

65. A device according to claim 63, where each access tool is maintained in a sterile state prior to deployment.

66. A device for delivering fluid to a patient, comprising:

an exit port assembly adapted to connect to a transcutaneous patient access tool;

an accumulator;

an inlet valve connected to an inlet of the accumulator;

a outlet valve connecting an outlet of the accumulator to the exit port assembly;

and

a priming mechanism for maintaining the inlet valve and the outlet valve simultaneously open.

67. A device according to Claim 66, wherein the priming mechanism comprises:

a pivotally movable first link operatively connected to the inlet valve of the dispenser such that the inlet valve is opened upon pivoting movement of the first link;

a pivotally movable second link operatively connected to the outlet valve of the dispenser such that the outlet valve is opened upon pivoting movement of the second link; and

a movable priming rod operatively connected to the first and the second links for pivoting the links upon movement of the rod.

68. A device according to Claim 67, wherein:

the inlet and the outlet valves each include a valve member movable between open and closed positions;

the first link extends between the valve member of the inlet valve and the priming rod and is pivotally movable about a pivot point of the first link located between the valve member of the inlet valve and the priming rod;

the second link extends between the valve member of the outlet valve and the priming rod and is pivotally movable about a pivot point of the second link located between the valve member of the outlet valve and the priming rod; and

the priming rod is linearly movable.

69. A device according to Claim 67, further comprising:

a fill port adapted to receive a needle; and

a collar connected to the priming rod and received in the fill port, the collar adapted to receive a needle inserted into the fill port so that the inserted needle causes movement of the collar and the priming rod and pivoting movement of the links.

70. A device according to Claim 66, further comprising at least two laminated layers of material defining the accumulator.

71. A device for delivering fluid to a patient, comprising:

a transcutaneous access tool having a known internal fluid volume;

a dispenser for delivering fluid from a reservoir to the access tool.

72. A device according to claim 71, further comprising a processor controlling the dispenser, and wherein the processor is programmed to cause the dispenser to deliver a volume of fluid equal to the known internal fluid volume of the access tool upon receiving a command.

73. A device according to claim 71, further comprising a flow detector positioned between the dispenser and the access tool.

74. A device according to claim 73, further comprising a processor controlling the dispenser and receiving signals from the flow detector, and wherein the processor is programmed to cause the dispenser to deliver a predetermined flow of fluid for a predetermined period upon receiving a command and upon receiving a signal from the flow detector indicative of an initial flow of fluid to the access tool, the predetermined flow of fluid for the predetermined period producing a volume of fluid substantially equal to the known internal fluid volume of the access tool.

75. A device according to claim 71, further comprising a fluid detector positioned between the dispenser and the access tool.

76. A device according to claim 75, further comprising a processor controlling the dispenser and receiving signals from the fluid detector, and wherein the processor is programmed to cause the dispenser to deliver a predetermined flow of fluid for a predetermined period upon receiving a command and upon receiving a signal from the fluid detector indicative of fluid initially entering the access tool, the predetermined flow of fluid for the predetermined period producing a volume of fluid substantially equal to the known internal fluid volume of the access tool.

77. A device for delivering fluid to a patient, comprising:

an exit port assembly connectable to a transcutaneous patient access tool;  
a dispenser for controlling fluid flow to the exit port assembly; and  
a gas removal filter connected to the dispenser for removing gas bubbles from  
fluid entering the dispenser.

78. A device according to Claim 77, further comprising a reservoir connected to the  
gas removal filter, and a fill port connected to the reservoir.

79. A device according to Claim 77, further comprising a reservoir connected  
between the gas removal filter and the dispenser, and a fill port connected to the gas removal  
filter.

80. A device for delivering fluid to a patient, comprising:

- A) a reservoir; and
- B) a fill port including,

a passageway in fluid communication with the reservoir,  
a valve positioned within the passageway and allowing one-way flow into  
the reservoir, and

a removable septum sealing the passageway.

81. A device according to Claim 80, wherein the fill port further comprises a funnel  
having a small open end removably received in the passageway and a large open end receiving  
the septum.

82. A device according to Claim 81, wherein the fill port further comprises a first wall having an opening removably receiving the large open end of the funnel when the small open end of the funnel is removably received in the passageway.

83. A device according to Claim 82, wherein the fill port further comprises a second wall spaced from the first wall more than a thickness of the septum and having an opening allowing passage of a needle and preventing passage of the septum.

84. A device according to Claim 80, wherein the fill port further comprises a first wall having an opening preventing passage of the septum, and a second wall spaced from the first wall at least about a thickness of the septum and having an opening allowing passage of a needle, and wherein the second wall and the opening of the second wall are adapted to allow passage of the septum upon at least a predetermined force applied to the septum.

85. A device according to Claim 84, wherein the predetermined force is less than a force required to pull a needle out of the septum.

86. A device for delivering fluid to a patient, comprising:

a plurality of transcutaneous access tools; and

a dispenser adapted to control fluid flow to the access tools;

wherein each access tool is independently deployable and adapted to provide fluid communication with the dispenser upon deployment.

87. A device according to claim 86, wherein each access tool comprises a needle.

88. A device according to claim 86, wherein each access tool includes:

a lumen connected to the dispenser; and

a lever secured to the access tool and arranged to deploy the access tool upon movement of the lever from a first position to a second position, the lever having an occlusion member arranged to occlude the lumen when the lever is in the first position.

89. A device according to claim 86, where each access tool is maintained in a sterile state prior to deployment.